IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION	
and BOSTON SCIENTIFIC SCIMED, INC.,)
Plaintiffs,)
v.) C.A. No. 05-768 (SLR)
CONOR MEDSYSTEMS, INC.,)
Defendant.)

OPENING BRIEF IN SUPPORT OF CONOR'S MOTION TO STAY

MORRIS, NICHOLS, ARSHT & TUNNELL Jack B. Blumenfeld (# 1014)
Roger D. Smith II (# 3778)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
Attorneys for Conor Medsystems, Inc.

Page 1 of 16

Of Counsel:

Matthew D. Powers Jared Bobrow WEIL, GOTSHAL & MANGES LLP 201 Redwood Shores Parkway Redwood Shores, CA 94065 (650) 802-3000

Sherry M. Knowles KING & SPALDING LLP 191 Peachtree Street Atlanta, GA 30303 (404) 572-4600

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TABLE OF CONTENTS

i.

		<u>Page</u>
TABLE OF (CITATIONS	ii
INTRODUC	TION	1
NATURE A	ND STAGE OF THE PROCEEDINGS	3
SUMMARY	OF THE ARGUMENT	3
STATEMEN	T OF FACTS	4
A.	Conor's Stent Development	4
B.	The Jang Ownership Lawsuit	5
C.	BSC's Lawsuit Against Conor	6
ARGUMEN	Γ	6
CONCLUSIO	ON	10

TABLE OF CITATIONS

	Page(s)
<u>Cases</u>	
Alloc, Inc. v. Unilin Decor N.V., 2003 U.S. Dist. LEXIS 11917 (D. Del. July 11, 2003)	10
Bayer AG v. Novartis Crop Prot., Inc., 2000 WL 1124513 (M.D. La. June 29, 2000)	8, 9
Consol. Aluminum Corp. v. Hi-Tech Ceramics, Inc., 1988 U.S. Dist. LEXIS 12482 (W.D.N.Y. Apr. 1, 1988)	9
Cordis Corp. v. Boston Scientific Corp., C.A. No. 03-27-SLR	1, 10
Honeywell Int'l Inc. v. Audiovox Comms. Corp., 2005 U.S. Dist. LEXIS 22933, *8 (D. Del. May 18, 2005)	7
<u>Landis v. North Am. Co.,</u> 299 U.S. 248 (1936)	6
Loral Fairchild Corp. v. Matsushita Elec. Indus. Co., Ltd., 840 F. Supp. 211 (E.D.N.Y. 1994)	7
Mediterranean Enters., Inc. v. Ssangyong Corp., 708 F.2d 1458 (9th Cir. 1983)	6
Santrade, Ltd. v. Gen. Elec. Co., 1990 U.S. Dist. LEXIS 19260 (E.D.N.C. Dec. 6, 1990)	7, 8
Summa Four, Inc. v. AT&T Wireless Servs., Inc., 994 F. Supp. 575 (D. Del. 1997)	7
United Merchs. & Mfrs., Inc. v. Henderson, 495 F. Supp. 444 (N.D. III 1980)	7
United Sweetener USA, Inc. v. Nutrasweet Co., 766 F. Supp. 212 (D. Del. 1991)	7
Wing Shing Prods. (BVI) Ltd. v. Simatelex Manufactory Co., 2005 U.S. Dist. LEXIS 6780 (S.D.N.Y. Apr. 19, 2005)	7
Wireless Spectrum Techs., Inc. v. Motorola Corp., 2001 U.S. Dist. LEXIS 239 (N.D. Ill. Jan. 10, 2001)	9

1.

Page 5 of 16

Defendant Conor Medsystems, Inc. ("Conor") submits this brief in support of its motion to stay this case pending resolution of related litigation in the United States District Court for the Central District of California, entitled <u>G. David Jang v. Boston Scientific Corp. et al.</u>, ED CV 05-00426 (VAP) (C.D. Cal.) (the "Jang Ownership Lawsuit").

Conor is a small medical device company with fewer than 200 employees worldwide. Conor's business involves developing innovative vascular drug delivery technology for treatment of coronary artery disease, including coronary stents. Conor has not received approval from the FDA to commercialize any stents in the United States. Conor is seeking such approval for its drug-eluting CoStarTM stent, but such approval is not likely to be obtained until late-2007 at the earliest. Conor has made some sales of its CoStar stent in certain countries that do not require regulatory approval. These sales, however, have not been significant, totaling less than \$1.4 million through September 30, 2005.

Plaintiffs Boston Scientific Corporation and Boston Scientific Scimed, Inc. (collectively, "BSC") filed this patent suit against Conor less than two months ago, on November 8, 2005. The complaint alleges that Conor has infringed U.S. Patent No. 5,922,021 (the "Jang '021 patent"). BSC is one of the world's largest manufacturers of coronary stents, with sales of its TAXUS stent system through September 30, 2005 of approximately \$1.9 billion.

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This is the same patent on which BSC and Cordis recently filed JMOL and new trial briefs in Cordis Corp. v. Boston Scientific Corp., C.A. No. 03-27-SLR. There, Cordis seeks JMOL or a new trial based on the grounds, inter alia, that Cordis's BX Velocity stent cannot infringe under the doctrine of equivalents because it does not have the required "corners"; that Cordis's stent cannot infringe because the '021 claims do not cover stents whose connected expansion strut pairs are 180° out of phase; that the asserted claim would have been obvious to one of ordinary skill in the art; and that BSC's counsel made improper arguments to the jury about copying.

By this motion, Conor urges the Court to stay this litigation pending resolution of the Jang Ownership Lawsuit. In that case, which has been set for trial in early 2007, Dr. Jang alleges that BSC obtained an assignment of the Jang '021 patent (and other patents) through fraud or mistake. Dr. Jang is asking the Central District of California to rescind the assignment and, thereby, divest BSC of any rights to enforce the '021 patent. BSC's complaint in this action alleges that it has rights to enforce the Jang '021 patent solely by virtue of an assignment from Dr. Jang. Thus, if Dr. Jang prevails in his California lawsuit, BSC would not have standing to proceed with this lawsuit.

Under these circumstances, a stay of this action pending resolution of the Jang Ownership Lawsuit would greatly benefit the Court, the parties, and the interests of justice. First, a stay will prevent Conor and this Court from expending their resources on a lawsuit that will have to be dismissed if Dr. Jang prevails in California. If this action is not stayed and BSC loses in California, then Conor and this Court will have wasted countless hours, resources, and attorney fees on motions, discovery, scheduling, and case management. Second, BSC would not be prejudiced in any significant way if this action were stayed. Conor has not received approval from the FDA to sell any stents in the United States, and Conor is not likely to receive such approval before late-2007 at the earliest -- long after the Jang Ownership Lawsuit is scheduled to be resolved. Third, the Jang Ownership Lawsuit is far ahead of this one and is set for trial on February 20, 2007. In contrast, this action has just begun. The parties have not conducted initial disclosures or discovery. The Court has not yet held a scheduling conference. Thus, no discovery cut-off date or trial date has been set. All of these factors weigh heavily in favor of a stay.

Page 7 of 16

NATURE AND STAGE OF THE PROCEEDINGS

BSC commenced this patent action against Conor on November 8, 2005. (D.I. 1.) The Complaint charges Conor with infringement of the Jang '021 patent. The Complaint asserts that Conor has made, used, offered to sell, or sold CoStar and UniStar stents in the United States beyond uses that are exempt from infringement under 35 U.S.C. § 271(e)(1).

Conor timely answered the complaint on December 30, 2005. (D.I. 8.) In its answer, Conor denied BSC's allegations, denied that it has infringed the '021 patent, and asserted a number of defenses, including defenses arising from Dr. Jang's claim in the Jang Ownership Lawsuit that BSC obtained an assignment of the Jang '021 patent through fraud or mistake. Discovery has not begun. Initial disclosures have not taken place. The Court has not conducted a scheduling conference and has not set dates for discovery cut-off, summary judgment, Markman hearing, pretrial conference, or trial.

SUMMARY OF THE ARGUMENT

This Court has the inherent power to stay an action to serve the interests of justice, to promote efficiency, and to preserve the resources of the Court and the parties. This lawsuit should be stayed pending resolution of the Jang Ownership Lawsuit in California. Such a stay would preserve the resources of the parties and the Court, and would promote efficiency, because the outcome of the Jang Ownership Lawsuit may very well be dispositive of this lawsuit. That is, if Dr. Jang prevails in the Jang Ownership Lawsuit and the assignment between BSC and Dr. Jang is rescinded, then this lawsuit would have to be dismissed, because BSC would not have standing to enforce the Jang '021 patent without the assignment. In addition, a stay would not materially prejudice BSC, because this case is just beginning, the Jang Ownership Lawsuit is set for trial in February 2007 (much earlier than this case would be set for trial), Conor has not been

approved to sell stents in the United States, and Conor will not receive approval to commercialize its CoStar stent in the United States until late 2007 at the earliest.

STATEMENT OF FACTS

A. Conor's Stent Development

Conor is a small medical device company with fewer than 200 employees. Declaration of Jeff Tillack ¶3. Conor's business involves the development of innovative vascular drug delivery technologies. <u>Id.</u> Conor has developed a bare metal stent called the UniStar and a drugeluting stent called the CoStarTM to treat coronary artery disease. Id.

Conor has not commercialized the CoStar or UniStar stents in the United States, as it has not received regulatory approval from the FDA to market any stent in the United States. Tillack Decl. ¶ 4; Declaration of Vicki Hacker ¶ 3.

Much of Conor's activity in the United States is directed at obtaining regulatory approval for its CoStar stent from the FDA. Hacker Decl. ¶ 3. In March 2005, the FDA gave Conor conditional investigational device exemption approval to conduct a U.S. pivotal clinical trial of its CoStar stent. Id. At this time, Conor expects to complete the necessary patient enrollment, clinical follow-up, and submission of clinical data to the FDA by the second quarter of 2007 at the earliest. Id. ¶ 4. Thereafter, the FDA will take additional time to review and (Conor hopes) approve the application to market the CoStar stent in the United States. Id. Conor has supplied CoStar stents in the United States and in Europe to obtain data that it has used to support its request for U.S. regulatory approval from the FDA. Tillack Decl. ¶ 5. The manufacture and use of CoStar stents in the United States for purposes of obtaining regulatory approval, including activities associated with clinical trials, plainly are exempt from patent infringement claims under 35 U.S.C. § 271(e)(1).

Page 9 of 16

Conor has sold a relatively small number of CoStar stents outside the United States on a commercial basis in certain countries that do not require regulatory approval. Tillack Decl. ¶ 6. The sale of these stents generated revenues of less than \$1.4 million through September 30, 2005. Exhibit A (Conor Form 10-Q) at 4.

B. The Jang Ownership Lawsuit

On May 19, 2005, G. David Jang filed the Jang Ownership Lawsuit against BSC in the Central District of California. Exhibit B (Jang Complaint). The Jang Ownership Lawsuit casts into doubt BSC's rights to enforce the Jang '021 patent against Conor in this lawsuit.

According to the complaint in California, Dr. Jang entered into an Assignment Agreement with BSC in June 2002 under which BSC obtained rights to Dr. Jang's coronary stent patents, including the Jang '021 patent. <u>Id.</u> ¶¶ 14-15 & Exh. 2 (Assignment Agreement, Schedule 2.1(a) (listing the '021 patent)). According to the complaint, however, BSC has wrongfully asserted an ownership interest in Dr. Jang's balloon catheter patents. <u>Id.</u> (¶ 18). Dr. Jang alleges that such an ownership interest was obtained through fraud, as BSC represented during negotiations that it did not wish to acquire the balloon catheter patents. Id. (¶¶ 25-27).

Significantly, Dr Jang seeks to rescind the Assignment on the ground that his consent to assign his patents was obtained by fraud. <u>Id.</u> (¶¶ 32-33). Thus, if Dr. Jang prevails in the Jang Ownership Lawsuit, BSC no longer would have rights to any of Dr. Jang's coronary stent patents, including the '021 patent at issue in this lawsuit, and would not be able to maintain this lawsuit against Conor.

On or about October 20, 2005, the Court entered a scheduling order in the Jang Ownership Lawsuit. Exhibit C (Docket Sheet, Item 34). Under the schedule, the discovery cut-off is set for October 13, 2006 and trial is set for February 20, 2007. Id.

C. BSC's Lawsuit Against Conor

Nearly six months after Dr. Jang filed the Jang Ownership Lawsuit, BSC filed this lawsuit in November 2005. (D.I. 1.) The lawsuit is in its infancy. Conor just filed its answer on December 30. (D.I. 8.) The parties have not commenced initial disclosures or discovery. The Court has not yet held a scheduling conference. There is no discovery cut-off date and no trial date.

BSC is one of the world's largest manufacturers of coronary stents. In the first three quarters of 2005, BSC generated revenues from sales of its TAXUS stent system of over \$1.9 billion. Exhibit D (BSC Form 10-Q) at 26. BSC, with all its sales and resources, plainly is in a better position to absorb attorney fees and costs than Conor. As Conor is developing new stents and expending resources to obtain regulatory approval, the cost of this patent infringement lawsuit will impose a hardship on Conor.

ARGUMENT

The Supreme Court has recognized that district courts have the inherent power to manage their dockets and stay proceedings. Landis v. North Am. Co., 299 U.S. 248, 254 (1936) ("[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants."). Based on this inherent power, courts regularly stay cases in favor of related but separate lawsuits, even when the related proceedings may not be controlling. Mediterranean Enters., Inc. v. Ssangyong Corp., 708 F.2d 1458, 1465 (9th Cir. 1983).

In exercising their discretion, district courts have stayed patent infringement cases when the ownership of the patent-in-suit is being challenged in a related federal proceeding. For example, in Wing Shing Prods. (BVI) Ltd. v. Simatelex Manufactory Co., 2005 U.S. Dist.

LEXIS 6780 (S.D.N.Y. Apr. 19, 2005), the plaintiff initiated a patent infringement action based on the defendant's alleged infringement of a design patent. The defendant moved to stay the lawsuit pending the outcome of an appeal from a prior bankruptcy court determination that the design patent was enforceable and that plaintiff, not the debtor in bankruptcy, owned the design patent. Even though the plaintiff had prevailed in bankruptcy court, the district court granted the defendant's stay motion, reasoning in part that the plaintiff's patent infringement claim "will fail if the Federal Circuit finds that [the debtor] was a co-inventor of the Patent, or otherwise has ownership rights to the Patent." <u>Id.</u> at *6.²

Case 1:05-cv-00768-SLR

A variety of factors are relevant to determining the propriety of a stay, including whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; whether a stay will simplify the issues and trial of the case; whether discovery is completed or a trial date has been set; and whether not entering a stay would create economic hardship for the parties or hinder the effective administration of justice. Honeywell Int'l Inc. v. Audiovox Comms. Corp., 2005 U.S. Dist. LEXIS 22933, *8 (D. Del. May 18, 2005) (citing United Sweetener USA, Inc. v. Nutrasweet Co., 766 F. Supp. 212, 217 (D. Del. 1991)); Xerox Corp. v. 3 Com Corp., 69 F. Supp. 2d 404, 406 (W.D.N.Y. 1999); United Merchs. & Mfrs., Inc. v. Henderson, 495 F. Supp. 444, 447 (N.D. Ill 1980) ("a district court must evaluate the possible damage, hardship and inequities to the parties to the lawsuit and the relationship of the stay to

Similarly, federal courts have stayed federal patent infringement cases in favor of state court proceedings when the state court proceedings on patent ownership may dispose of the federal claims. Summa Four, Inc. v. AT&T Wireless Servs., Inc., 994 F. Supp. 575, 584, 585 (D. Del. 1997); Loral Fairchild Corp. v. Matsushita Elec. Indus. Co., Ltd., 840 F. Supp. 211, 215-16 (E.D.N.Y. 1994); Santrade, Ltd. v. Gen. Elec. Co., 1990 U.S. Dist. LEXIS 19260, at *4-*5 (E.D.N.C. Dec. 6, 1990).

fulfillment of judicial objectives of simplification of the issues in question and trial of the case."); Bayer AG v. Novartis Crop Prot., Inc., 2000 WL 1124513 (M.D. La. June 29, 2000).

Here, the relevant factors favor staying this lawsuit pending resolution of the Jang Ownership Lawsuit.

First, a stay would greatly promote the interests of judicial efficiency and economy, because the Jang Ownership Lawsuit may dispose of this case entirely. In its complaint, BSC alleges that it is the assignee of the Jang '021 patent and, from that assignment, has rights to enforce the Jang '021 patent. D.I. 1 ¶ 8. The Jang Ownership Lawsuit goes to the very heart of this lawsuit, because Dr. Jang is challenging the sole basis for BSC's standing to sue Conor, namely, the validity of the Assignment to BSC. If Dr. Jang prevails and the Central District of California rescinds the Assignment, BSC will not have standing to maintain this lawsuit against Conor. Given that the Court will have to dismiss this lawsuit if the Central District of California rescinds the Assignment, the interests of efficiency and judicial economy strongly favor a stay of this action. Santrade, 1990 U.S. Dist. LEXIS 19260, at *4 (staying a patent infringement case pending resolution of ownership issue in state court would "conserve[] the time and resources of the parties, counsel, and the courts" should plaintiff lose the ownership case).

Second, a stay would not unduly prejudice BSC. Conor has not received approval to commercialize any stents in the United States. Moreover, Conor does not expect to receive FDA approval to commercialize CoStar stents in the United States until late-2007 at the earliest. By that time, the Jang Ownership Lawsuit will have been decided, as a trial date in that case is set for February 20, 2007. Moreover, Conor's sales of stents outside the United States have not been significant (less than \$1.4 million through September 30, 2005). See Exhibit A (Conor Form 10-Q) at 4. Such a small volume of sales does not threaten BSC's market position. During the same period that Conor sold \$1.4 million of stents, BSC sold nearly \$2 billion of its TAXUS stents – some 1400 times as much as Conor.

Third, forcing Conor to litigate this case when it has not received regulatory approval to commercialize the accused products in the United States would impose a substantial hardship on Conor. While it is investing money in clinical trials, Conor is losing money. Its costs far exceed its revenues at this stage (Conor experienced a net loss of approximately \$38 million for the nine-month period ending September 30, 2005). See Exhibit A (Conor Form 10-Q) at 4, 5. Conor submits that it should not be forced to expend millions of dollars litigating this case through 2007, only to have the lawsuit dismissed if Dr. Jang prevails in California. Bayer, 2000 WL 1124513 at *3 (the court "finds that there is no reason why litigation between the same parties, embracing common issues, should be prosecuted simultaneously. To do so would create an economic hardship on the parties and also result in the ineffective administration of justice. It seems more efficient to allow the administrative study of the patent to conclude before this matter moves toward trial."); Wireless Spectrum Techs., Inc. v. Motorola Corp., 2001 U.S. Dist. LEXIS 239, *5 (N.D. Ill. Jan. 10, 2001) ("The Court finds that the equities favor a stay. The Court agrees with Motorola that a stay will further the interests of judicial economy and the conservation of the parties' resources."); Consol. Aluminum Corp. v. Hi-Tech Ceramics, Inc., 1988 U.S. Dist. LEXIS 12482 (W.D.N.Y. Apr. 1, 1988) (holding that granting a stay of the present proceedings, while awaiting a decision in another suit, would work a valuable conservancy of the court's and the parties' time and effort).

Fourth, this case is in its infancy. BSC filed its Complaint on November 8, 2005 and Conor just answered. Initial disclosures have not yet been exchanged, no discovery has been conducted, the Court has not conducted a scheduling conference, and no trial date has been set.

These facts, too, favor a stay. See Alloc, Inc. v. Unilin Decor N.V., 2003 U.S. Dist. LEXIS 11917, *8 (D. Del. July 11, 2003) ("court notes that discovery in this case has not yet begun, nor has a discovery schedule been entered at this time. Likewise, the court has not yet set a trial date. Therefore, the stay will be entered before any party incurs substantial litigation-related expenses.").

Conor is aware that the Court previously denied Cordis's motion in Cordis v. Boston Scientific, C.A. No. 03-27-SLR, to stay BSC's counterclaim for 60 days pending joinder of Dr. Jang as a party. Conor respectfully urges, however, that the facts which led to the Court's decision in Cordis differ significantly from the facts relevant today. For example, Cordis filed its motion on June 7, 2005, just days before trial was scheduled to begin. (D.I. 342 in C.A. No. 03-27-SLR.) The Court and the parties in Cordis already had spent substantial time and resources preparing for trial. Here, because this case just started, neither the Court nor the parties has invested significant resources. In addition, when Cordis filed its motion, the Jang Ownership Lawsuit was in its infancy. Here, in contrast, the Jang Ownership Lawsuit was filed long before this suit and the Court in California has conducted a scheduling conference, set a discovery cut-off date, and set a trial date. Further, Cordis -- part of the multi-billion dollar Johnson & Johnson company -- is a major competitor of BSC, with hundreds of millions of dollars of stent sales annually. In constrast, Conor is not approved to sell stents in the United States and its sales overseas are insignificant.

CONCLUSION

Conor respectfully requests that this Court stay this action pending resolution of the Jang Ownership Lawsuit.

MORRIS, NICHOLS, ARSHT & TUNNELL

/s/ Jack B. Blumenfeld (#1014)

Jack B. Blumenfeld (# 1014) Roger D. Smith II (# 3778) MORRIS, NICHOLS, ARSHT & TUNNELL 1201 North Market Street P.O. Box 1347 Wilmington, DE 19899-1347 (302) 658-9200 jblumenfeld@mnat.com Attorneys for Conor Medsystems, Inc.

Of Counsel:

Matthew D. Powers Jared Bobrow WEIL, GOTSHAL & MANGES LLP 201 Redwood Shores Parkway Redwood Shores, CA 94065 (650) 802-3000

Sherry M. Knowles KING & SPALDING LLP 191 Peachtree Street Atlanta, GA 30303 (404) 572-4600

January 3, 2006

CERTIFICATE OF SERVICE

I, Jack B. Blumenfeld, hereby certify that on January 3, 2006, I caused to be electronically filed with the Clerk of the Court Opening Brief in Support of Conor's Motion to Stay using CM/ECF, which will send notification of such filing(s) to the following:

Josy W. Ingersoll Young, Conaway, Stargatt & Taylor, LLP

and that I caused copies to be served upon the following in the manner indicated:

BY HAND

Josy W. Ingersoll Young, Conaway, Stargatt & Taylor, LLP 1000 West Street, 17th Floor Wilmington, DE 19899

BY FEDERAL EXPRESS

Peter J. Armenio Kirkland & Ellis Citigroup Center 153 East 53rd Street New York, NY 10022

/s/ Jack B. Blumenfeld (#1014)
Morris, Nichols, Arsht & Tunnell
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com